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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ASSOCIATION FOR ACCESSIBLE MEDICINES, Plaintiff, - against - BARBARA D. UNDERWOOD, in her official capacity as acting Attorney General of the State of New York; and HOWARD A. ZUCKER, in his official capacity as Commissioner of Health of the State of New York, Defendants.	CASE NO. **COMPLAINT**

Plaintiff Association for Accessible Medicines ("AAM") brings this complaint for declaratory and injunctive relief against Barbara D. Underwood, in her official capacity as Attorney General for the State of New York (the "Attorney General"), and Howard A. Zucker, in his official capacity as Commissioner of the Department of Health of the State of New York (the

"Commissioner," and, collectively with the Attorney General, "Defendants"). AAM brings this complaint based on personal knowledge as to all AAM facts, and on information and belief as to all other matters.

PRELIMINARY STATEMENT

1. The opioid epidemic is a national crisis. "Opioids were responsible for approximately 42,000 of the 64,000 drug overdose deaths" in the United States in 2016. Drug Enforcement Administration, *DEA Bolsters Fight Against Opioid Crisis With 250 Additional Task Force Officers* (Mar. 26, 2018), https://bit.ly/2pT4zz2. Both of those figures were all-time highs, *id.*, as were the opioid-related death totals in each of the previous two years, *see* White House Press Release Archives, *Continued Rise in Opioid Overdose Deaths in 2015 Shows Urgent Need for Treatment* (Dec. 8, 2016), https://bit.ly/2ybN8RT.

2. AAM is fully committed to efforts to address the opioid epidemic. Indeed, AAM has even pioneered some programs of its own. AAM recently partnered with a leading education technology company to produce a nationwide educational initiative that has already helped tens of thousands of college students gain the skills to make safe and healthy decisions about prescription medications and understand the dangers of misusing these drugs. AAM also supports initiatives to assist physicians and other prescribers in the proper prescribing of opioids, as well as consideration of limits on opioids prescriptions for acute pain. *See* Test. of Jeffrey K. Francer, Senior Vice President & General Counsel, Ass'n for Accessible Medicines, to the U.S. House of Representatives Comm. on Energy & Commerce, Subcomm. on Health (Mar. 21, 2018), https://bit.ly/2Mwbz2s.

3. But even the most desirable laws must comply with the Constitution. And here, a component of New York's recently enacted Opioid Stewardship Act (the "Act") does not.

4. Added as a new title 2-A to Article 33 of New York's public health law, the Act establishes an "opioid stewardship fund" (the "Fund"), N.Y. Pub. Health Law § 3323(1), which New York intends to use to finance treatment programs and other opioid relief initiatives, *see* N.Y. State Fin. Law § 97-aaaaa(2), (4). Under the Act, "the total amount" of the Fund—$100 million per year—is "to be paid" solely by the manufacturers and distributors that lawfully sell opioids in the State of New York ("licensees"). N.Y. Pub. Health Law § 3323(1)(a); *see* § 3323(2), (3). The Act also seeks to compel licensees to internalize the full financial cost of the legislation. To that end, the Act prohibits licensees from "pass[ing] on" "*any portion*" of "the cost of their" share of the Fund to *any* "purchaser," whether an upstream wholesale distributor or "the ultimate user of the opioid." § 3323(2), (10)(c) (emphasis added). Licensees found to have violated that prohibition "shall be subject to penalties" of up to "one million dollars per incident." *Id.*

5. Again, AAM does not object to New York's decision to address the opioid crisis head on. But the Act's prohibition on passing on any portion of the cost of the Fund to anyone, anywhere, in any way, is a bridge too far under our Constitution. Under the Act, if an opioid manufacturer increased the price it charges its distributors for any of its products—including its *non*-opioid products—by a penny a pill (or a penny a thousand) in an attempt to defray the cost of the Fund, then the manufacturer would be subject to million-dollar New-York-law penalties, *even if all of the manufacturer's sales to its distributors took place entirely outside of New York*.

6. That New York cannot do. The Supreme Court has long held that states lack the "power to project [their] legislation into [another state] by regulating the price to be paid in that state for [goods or services] acquired there," *Baldwin v. G.A.F. Seelig. Inc.*, 294 U.S. 511, 521 (1935), as the "'Commerce Clause … precludes the application of a state statute to commerce that takes place wholly outside of the State's borders, whether or not the commerce has effects within

the State,'" *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989) (quoting *Edgar v. MITE Corp.*, 457 U.S. 624, 642-43 (1982) (plurality opinion)), and "regardless of whether the statute's extraterritorial reach was intended by the legislature," *id.* Yet that is precisely what the Act's anti-pass-through provisions do. By prohibiting all price increases anywhere that are undertaken in response to the cost of financing the State of New York's Fund, including those transactions that occur entirely outside of New York, the Act plainly regulates the prices that can be charged in other states.

7. Yet even if the Act's anti-pass-through provisions can be read to apply only where licensees pass on a portion of the cost of their ratable share payments to purchasers *in New York*, the Act still violates the Commerce Clause. "The Commerce Clause presumes a national market free from local legislation that discriminates in favor of local interests," *C & A Carbone, Inc. v. Town of Clarkstown*, 511 U.S. 383, 393 (1994), and accordingly "limits the power of the [states] to adopt regulations that discriminate against interstate commerce," *W. Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 192 (1994). A law that raises costs on private parties but precludes them from shifting "any portion" of those costs onto New York purchasers will have an obvious practical effect: the regulated entities will "attempt to recoup" at least some portion of the cost of the regulation "at the expense of non-New York purchasers of their products." *Shell Oil Co. v. N.Y. State Tax Comm'n*, 91 A.D.2d 81, 92 (N.Y. App. Ct. 1983). In other words, "the practical effect of the prohibition is to shift the direct burden of the [opioid stewardship fund payments] from the companies' New York customers to their out-of-State customers." *Id.* at 93. That "practical effect" violates the Commerce Clause's antidiscrimination principle. *See, e.g.*, *Maryland v. Louisiana*, 451 U.S. 725, 756-57 (1981).

8. For these reasons, and as explained below, AAM seeks an injunction against the implementation and enforcement of the Act's anti-pass-through provisions (N.Y. Pub. Health Law

§ 3323(2), (10)), a declaration that the Act's anti-pass-through provisions are unconstitutional and invalid, and any other relief this Court deems appropriate. AAM wishes to emphasize, however, that it is merely challenging this aspect of the Act, which will not invalidate New York's Fund or other important opioid mitigation activities.

PARTIES

9. AAM is a nonprofit, voluntary association representing the leading manufacturers and distributors of generic and biosimilar medicines, manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medications. To that end, AAM's members provide American consumers with generic drugs that are just as safe and effective as their brand-name counterparts, but substantially less expensive. Indeed, generic drugs like those produced by AAM's members save patients, payers, and taxpayers nearly $5 billion *every single week*. Ass'n for Accessible Meds., *2017 Generic Drug Access & Savings in the U.S.* at 34, https://bit.ly/2ua5ugE. Unlike brand-name drug manufacturers, AAM's member companies typically do not market and promote their generic products to physicians and patients. That is because physicians and patients usually do not control whether a prescription is filled with a particular generic product. Rather, physicians generally write prescriptions for their patients for brand-name drugs; the generic products are then substituted for the more expensive products by pharmacists. AAM's members include multiple manufacturers of generic opioids. Because of the different manner in which generic companies operate, generic manufacturers have not been the main focus of the recent allegations of abusive sales and marketing practices related to opioid products. AAM is authorized by its Board of Directors to bring this suit on its members' behalf.

10. Defendant Barbara D. Underwood is the acting Attorney General of New York. In that capacity, she has the authority to investigate and prosecute violations of the laws of the State of New York, N.Y. Exec. Law § 63, and has power to "bring an action for an injunction against any person who violates, disobeys or disregards any term or provision of" the New York Public Health Law, including the Act. N.Y. Pub. Health Law § 12.

11. Defendant Howard A. Zucker is the New York Commissioner of Health (the "Commissioner"). The Commissioner serves as the head of the New York Department of Health, N.Y. Pub. Health Law § 206(a), and in that capacity "enforce[s] the public health law," *id.* § 206(f). The Commissioner also oversees the Department's administration of the Act and has the specific authority to "impose a penalty not to exceed one million dollars per incident" on any manufacturer or distributor that has "passed on" its "ratable share, or any portion thereof … to a purchaser," including the ultimate user of the medications. *Id.* § 3323(10)(c).

12. The Attorney General and the Commissioner, as well as those subject to their supervision, direction, and/or control, are responsible for enforcement of the Act.

JURISDICTION AND VENUE

13. AAM's causes of action arise under 42 U.S.C. § 1983 and the United States Constitution. The Court has jurisdiction under 28 U.S.C. § 1331.

14. Venue is appropriate in this district pursuant to 28 U.S.C. § 1391(b).

15. There is a justiciable Case or Controversy. AAM's claims do not require the participation of AAM's individual members. AAM fulfills its purposes in part through litigation against governmental authorities to defend AAM members from damaging and unconstitutional laws, and the Act injures members whose opioids are sold and prescribed in New York by subjecting them to unconstitutional requirements. In particular, because AAM's members subject

to the Act cannot absorb the entire cost of financing the Fund, operation of the Act forces members either to violate the statute or to raise at least some of the prices of at least some of their products.

BACKGROUND

Generic Drugs Are Sold, And Priced, Nationally

16. Like most generic prescription drug manufacturers, most AAM member manufacturers, including those that manufacture and sell generic opioid products, produce multiple types of generic drugs.

17. AAM members sell nearly all of their products to two types of purchasers: (1) large, national wholesale distributors; and (2) national retail pharmacy chains that warehouse the products themselves. In fact, four national purchasing groups now control 90% of generic drug sales nationally. *See Meet The Power Buyers Driving Generic Drug Deflation (rerun)*, Drug Channels (July 27, 2018), https://bit.ly/2MowRyO.

18. AAM members most often sell their products in bulk contracts covering a range of products, rather than in single-drug or single-product contracts.

19. Decisions relating to the pricing and distribution of the generic drugs manufactured by AAM's members, including generic opioids, are generally made at a national, not state-by-state, level. Indeed, "[t]he pricing of prescription drugs and the flow of money among the various links in the pharmaceutical supply chain is more complex than the physical distribution of drugs through the chain." The Henry J. Kaiser Family Found., *Follow the Pill: Understanding the U.S. Commercial Pharm. Supply Chain* at 24 (Mar. 2005), https://bit.ly/2JzIjHk. As a result, state laws that impose price and cost regulations on generic pharmaceuticals invariably affect commercial transactions, pricing, and commerce in other states. Likewise, state laws that impose price and cost regulations on one particular type of generic drug invariably affect commercial transactions, pricing, and commerce involving other types of generic drugs.

The Opioid Stewardship Act

20. The Act establishes the Fund in the amount of "one hundred million dollars annually." N.Y. Pub. Health Law § 3323(1)(a), (3). The Fund is not financed by the State. The total $100-million annual amount is to be funded solely by the manufacturers and distributors that lawfully sell and distribute opioids in New York. *See id.* § 3323(5)(a).

21. To that end, the Act requires "each manufacturer and distributor" that lawfully "sells or distributes opioids in the state of New York" to pay into the Fund. *Id.* § 3323(1)(b); *see id.* § 3323(2) ("All manufacturers and distributors licensed under this article … that sell or distribute opioids in the state of New York shall be required to pay an opioid stewardship payment."); *id.* § 3323(5) ("Each manufacturer and distributor licensed under this article that sells or distributes opioids in the state of New York shall pay a portion of the total opioid stewardship payment amount.").

22. The Act contains a complex formula for determining each licensee's "individual portion" (or "ratable share") of the $100-million annual fund. The primary determinant of each licensee's ratable share is the "total amount" of morphine milligram equivalents ("MMEs") the licensee "sold or distributed in the state of New York" in the previous calendar year. *Id.* § 3323(1)(b), (5)(a)-(b). In order "to determine the … percentage" of the $100-million annual Fund each company owes, each company's "total amount of MMEs … shall be divided by the total amount of MME sold in the state of New York by all" manufacturers and distributors that lawfully sell or distribute opioids in New York. *Id.* § 3323(5)(a). That percentage, "multiplied by the total opioid stewardship payment" of $100 million per year, is the primary determinant in each manufacturer and distributor's ratable share payment. *Id.*

23. However, each licensee's respective share of the total amount of MMEs sold or distributed in New York is not the sole determinant of each licensee's respective ratable share payment. Opioids "sold or distributed to entities certified to operate pursuant to article thirty-two of the mental hygiene law, or article forty of the public health law" "shall not" be included in the MME or ratable share calculation; nor shall "the MMEs attributable to buprenorphine, methadone or morphine." *Id.* § 3323(5)(b).

24. Further, the New York Department of Health (the "Department") "shall have the authority to adjust the total number of a licensee's MMEs to account for the nature and use of the product, as well as the type of entity purchasing the product from the licensee, when making such determination and adjust the ratable share accordingly." *Id.* § 3323(5)(a).

25. In order to determine each licensee's ratable share of the $100-million annual Fund, the Act requires each manufacturer and distributor that lawfully sells or distributes opioids in the state to "provide to the commissioner a report detailing all the opioids sold or distributed by such manufacturer or distributor in the state of New York." *Id.* § 3323(4). The report must include the company's "gross receipt total … of all opioids sold or distributed" in New York in the previous year. *Id.* § 3323(4)(d). The report must also include "the number of containers … sold or distributed" in the previous year, "the total number of morphine milligram equivalents (MMEs) sold or distributed" in the previous year, and "any other elements as deemed necessary by the Commissioner." *Id.* § 3323(4)(f)-(h).

26. The report covering 2017 data was required to "be submitted by August 1, 2018." *Id.* § 3323(4-a). The Department has issued notice that it "will calculate ratable shares of the assessment based on the reported data, and will issue invoices for the ratable shares of the assessment to each licensee by October 15, 2018." Letter from Joshua S. Vinciguerra (May 15,

2018) ("*Dear Manufacturers* Letter"), https://on.ny.gov/2LLCDe9. The first payment, covering opioid sales during calendar year 2017, is due on January 1, 2019. Payments are due thereafter on a quarterly basis. N.Y. Pub. Health Law § 3323(6).

27. The Act affords manufacturers and distributors the chance to appeal a Commission decision as to their share of the $100-million annual Fund. *Id.* § 3323(8).

28. Licensees that fail to timely provide reports and records or fail to pay their annual share of the $100-million annual Fund are subject to a range of penalties. The Act imposes a penalty of up to $1,000 per-day for failure to timely provide annual reports. *Id.* § 3323(10)(a). If a licensee underreports or underpays its annual share of the Fund, then "a penalty of no less than ten percent and no greater than three hundred percent" of the licensee's share, plus "any other civil or criminal penalty provided by a law," may be assessed. *Id.* § 3323(10)(b).

29. The Act forbids manufacturers and distributors from passing on the cost of their ratable share of the Fund to any subsequent purchasers of their products. "No licensee shall pass the cost of their ratable share amount to a purchaser, including the ultimate user of the opioid, or such licensee shall be subject to penalties pursuant to subdivision ten of this section." *Id.* § 3323(2). Consistent with that prohibition, the Act subjects companies to "a penalty not to exceed one million dollars" whenever "any portion" of a manufacturer or distributor's "ratable share" of the $100-million annual payment "has been passed on to a purchaser." *Id.* § 3323(10)(c). A penalty of up to $1 million for passing on "any portion" of a manufacturer or distributor's ratable share may be imposed on a "per incident" basis. *Id.* Neither the prohibition nor the penalty is limited to a manufacturer or distributor's passing on the cost of its ratable share to purchasers in New York.

30. Finally, the Act contains a severability clause: "If any clause, sentence, paragraph, subdivision, or section … shall be adjudged by any court of competent jurisdiction to be invalid, such judgment shall not affect, impair, or invalidate the remainder thereof, but shall be confined in its operation to the clause, sentence, paragraph, subdivision, or section directly involved in the controversy in which such judgment shall have been rendered." N.Y. Pub. Health Law, art. 33, tit. 2-A, § 4; *see also id.* ("It is hereby declared to be the intent of the legislature that this act would have been enacted even if such invalid provisions had not been included herein.").

31. After the Act's enactment, the Department issued guidance on the interpretation and application of the Act (the "Guidance"). According to the Department, the Act's prohibition on "pass[ing] any portion of the ratable share to the purchaser … is not intended to apply to price increases that are attributable to other ordinary changes in manufacture or distribution costs." N.Y. State Opioid Annual Assessment Reporting Guidance, *available at* https://on.ny.gov/2oMSXgM. The Guidance did not define "other ordinary changes in costs." Nor did the Guidance clarify what constitutes an "incident" under § 3323(10), or whether the Act's anti-pass-through provisions apply to "incidents" beyond the boundaries of the State of New York.

Constitutional Limitations on Extraterritorial State Regulation

32. The Framers "intended that the States retain many essential attributes of sovereignty," and the "sovereignty of each State, in turn, implie[s] a limitation on the sovereignty of all of its sister States." *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 293 (1980). That limitation takes many forms, but one is paramount: Because "each State has a sovereignty that is not subject to unlawful intrusion by other States," *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 884 (2011) (plurality opinion), "[n]o State can legislate except with reference to its own jurisdiction," *Bonaparte v. Appeal Tax Court of Balt.*, 104 U.S. 592, 594 (1881)). *See also BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 571 (1996) ("[O]ne State's power to impose burdens on"

nonresidents "is not only subordinate to" Congress' power to regulate interstate commerce, "but is also constrained by the need to respect the interests of other States.").

33. Consistent with that design, the Supreme Court has "long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute." *United Haulers Ass'n, Inc. v. Oneida-Herkimer Solid Waste Mgmt. Auth.*, 550 U.S. 330, 338 (2007); *see* U.S. Const. art. I, § 8, cl. 3 ("The Congress shall have Power … [t]o regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes.").

34. Under that "implicit restraint," a state law that regulates commerce occurring "wholly outside of the State's borders … exceeds the inherent limits of the enacting State's authority," and will generally be struck down "whether or not the regulated commerce has effects within the State." *Healy*, 491 U.S. at 336 (citation omitted); *see, e.g.*, *Baldwin v. G.A.F. Seelig. Inc.*, 294 U.S. 511, 521 (1935) (invalidating under Commerce Clause a New York milk price law that had the effect of "regulating the price" of milk purchased outside of New York); *Am. Booksellers Found. v. Dean*, 342 F.3d 96, 102-04 (2d Cir. 2003) (invalidating under Commerce Clause a Vermont law that had the effect of regulating the prices of "sales in … neighboring state[s]"). In short, a state may not regulate "the terms of transactions that occur elsewhere." *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 669 (2003).

35. Nor may a state enact or enforce laws that have "'*the practical effect*' of regulating commerce occurring wholly outside [the] State's borders." *Healy*, 491 U.S. at 332 (emphasis added). A state statute that "has the practical effect of requiring out-of-state commerce to be conducted at the regulating state's direction" thus violates the Commerce Clause, *Brown & Williamson Tobacco Corp. v. Pataki*, 320 F.3d 200, 208-09 (2d Cir. 2003), regardless of whether that extraterritorial reach is plain from the face of the statute, *see C & A Carbone, Inc. v. Town of*

Clarkstown, 511 U.S. 383, 394 (1994) (invalidating ordinance that did not "regulate interstate commerce" "in explicit terms" but "nonetheless" did so "by its practical effect and design"), and "regardless of whether the statute's extraterritorial reach was intended by the legislature," *Healy*, 491 U.S. at 336.

Constitutional Limitations on State Laws that Discriminate Against Interstate Commerce

36. In addition to protecting against "the projection of one state regulator regime into the jurisdiction of another State," *Healy*, 491 U.S. at 336-37, the Commerce Clause also "prohibits economic protectionism—that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors." *New Energy Co. of Ind. v. Limbach*, 486 U.S. 269, 273 (1988). Indeed, a core "purpose of the Commerce Clause was to create an area of free trade among the several States." *McLeod v. J. E. Dilworth Co.*, 322 U.S. 327, 330 (1944) (Rutledge, J., dissenting). "State regulations affecting interstate commerce, whose purpose or effect is to gain for those within the state an advantage at the expense of those without," therefore violate the Commerce Clause. *S.C. State Highway Dep't v. Barnwell Bros.*, 303 U.S. 177, 184 n.2 (1938).

37. The "paradigmatic example of a law discriminating against interstate commerce is the protective tariff or customs duty," which "simultaneously raises revenue and benefits local producers by burdening their out-of-state competitors." *W. Lynn Creamery, Inc. v. Healy*, 512 U.S. 186, 193 (1994). But tariffs, which on their face discriminate against interstate commerce, are not the only type of law that may run afoul of the Commerce Clause anti-discrimination principle. State laws may also discriminate unconstitutionally against interstate commerce "in their effect." *Brown & Williamson*, 320 F.3d at 209.

38. A statute that "shifts the costs of regulation onto other states, permitting in-state lawmakers to avoid the costs of their political decisions," discriminates against interstate commerce. *Id.* at 208 (citing *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 108 (2d Cir. 2001)). So too does a statute that "alters the interstate flow of the goods in question, as distinct from the impact on companies trading in those goods." *Id.* at 208-09 (citing *Exxon Corp. v. Maryland*, 437 U.S. 117, 127 (1978)).

39. A state law that "unambiguously discriminates in its effect … almost always is 'invalid *per se*.'" *Id.* at 209 (quoting *Sorrell*, 272 F.3d at 108); *see Allco Finance Ltd. v. Klee*, 861 F.3d 82, 103 (2d Cir. 2017) ("A law that clearly discriminates against interstate commerce in favor of intrastate commerce is virtually invalid *per se* and will survive only if it is 'demonstrably justified by a valid factor unrelated to economic protectionism.'" (quoting *Town of Southold v. Town of E. Hampton*, 477 F.3d 38, 47 (2d Cir. 2007))). Courts may uphold a discriminatory state law only if it "advances a legitimate local purpose that cannot be adequately served by reasonable nondiscriminatory alternatives." *Dep't of Revenue of Ky. v. Davis*, 553 U.S. 328, 338 (2008) (quoting *Or. Waste Sys., Inc. v. Dep't of Envtl. Quality of State of Or.*, 511 U.S. 93, 101 (1994)).

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
(Declaratory/Injunctive Relief—Unconstitutionality of the Act's Anti-Pass-Through Provisions under the Commerce Clause's Anti-Extraterritoriality Principle)

40. AAM re-alleges and incorporates by reference the preceding allegations as though fully set out herein.

41. "In reviewing whether a statute violates the dormant Commerce Clause, the 'threshold' question … is 'whether a state or local government is regulating.'" *Brown & Williamson*, 320 F.3d at 208 (quoting *United Haulers*, 261 F.3d at 254). "'[A] state regulates when

it exercises governmental powers that are unavailable to private parties,' such as the imposition of civil or criminal penalties to compel behavior." *Id.* (quoting *United Haulers*, 261 F.3d at 255).

42. The anti-pass-through provisions of the Act clearly "regulate" manufacturers and distributors of opioids. Only the sovereign has the power to require private entities to pay into a fund, and only the sovereign has the power to impose "penalties" of up to "one million dollars" on private entities that "pass[] on" to purchasers "any portion of" "the cost of their ratable share" of the Fund. N.Y. Pub. Health Law § 3323(2), (10).

43. "If a statute 'regulates,' then the second question … is whether the statute, in 'regulating,' 'affects interstate commerce.'" *Brown & Williamson*, 320 F.3d at 208 (quoting *United Haulers*, 261 F.3d at 254). In answering that question, a state law that has "the practical effect" of "control[ling] conduct beyond the boundaries of the State" is treated the same as a state law that controls out-of-state commerce by its plain terms. *Healy*, 491 U.S. at 336. In either case, the law violates the Commerce Clause.

44. In reviewing a state law that regulates commercial activity, "the practical effect of the statute must be evaluated not only by considering the consequences of the statute itself, but also by considering how the challenged statute may interact with the legitimate regulatory regimes of other States and what effect would arise if not one, but many or every, State adopted similar legislation." *Id.*

45. On its face, the Act does not limit its prohibition on "pass[ing] on" the cost of a licensee's ratable share payments to the pricing of opioids that are sold or consumed inside New York. N.Y. Pub. Health Law § 3323(10). The Act's anti-pass-through provisions instead prohibit and penalize licensees for "pass[ing] on" the cost of their ratable share payments to any "purchaser" anywhere, *i.e.*, even by increasing the prices of opioids that are manufactured, sold,

and consumed entirely outside New York. Indeed, the law even prohibits and penalizes licensees for "pass[ing] on" the cost of their ratable share payments by increasing the prices of their *non*-opioid products, again without regard to the location of those sales. *Id*.

46. A state law that attaches in-state penalties to the out-of-state pricing of goods or services has the practical effect of regulating "the price to be paid" out of state for those goods or services, in violation of the Commerce Clause. *Baldwin*, 294 U.S. at 521; *cf. BMW of N. Am.*, 517 U.S. at 572 ("[A] State may not impose economic sanctions on violators of its laws with the intent of changing the tortfeasors' lawful conduct in other States.").

47. To be sure, "manufacturers will rarely be able to fully pass through to consumers the costs of a new … regulation," so the simple fact "that manufacturers must bear some of the costs of the [New York] regulation in the form of lower profits does not cause the statute to violate the Commerce Clause." *Sorrell*, 272 F.3d at 110-11. But a state regulation that explicitly *forbids* manufacturers from seeking to defray those costs even from purchasers outside the state has a different valence altogether. In that case, as here—where the Act prohibits licensees from passing on "any portion" of the cost of their ratable share payments even to purchasers outside New York—manufacturers *are* "required to adhere to the [New York] rule in other states." *Id.* at 111.

48. The Act accordingly violates the Commerce Clause, because it has the practical effect of regulating commerce beyond the boundaries of New York.

SECOND CAUSE OF ACTION
(Declaratory/Injunctive Relief—Unconstitutionality of the Act's Anti-Pass-Through Provisions under the Commerce Clause's Anti-Discrimination Principle)

49. AAM re-alleges and incorporates by reference the preceding allegations as though fully set out herein.

50. A state regulation violates the Commerce Clause to the extent it "unambiguously discriminates" against interstate commerce "in its effect." *Brown & Williamson*, 320 F.3d at 209.

51. Discrimination in violation of the Commerce Clause is not limited to state laws that benefit in-state companies while simultaneously denying benefits to out-of-state companies. State laws that differentiate between in-state and out-of-state *consumers* in a way that benefits only the former run afoul of the Commerce Clause as well. *See, e.g.*, *Chem. Waste Mgmt. v. Hunt*, 504 U.S. 334, 334 n.6 (1992); *Or. Waste Sys.*, 511 U.S. at 99.

52. "The party challenging the validity of a statute bears the burden of showing that it is discriminatory." *Brown & Williamson*, 320 F.3d at 209. If "discrimination against commerce … is demonstrated, the burden falls on the State to justify it both in terms of the local benefits flowing from the statute and the unavailability of nondiscriminatory alternatives adequate to preserve the local interests at stake." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 353 (1977).

53. To the extent the Act's anti-pass-through provisions may be read not to apply to prices charged outside of New York—*i.e.*, as prohibiting and penalizing the passing on of the cost of a licensee's ratable share payment only to purchasers in New York—"the practical effect of the prohibition is to shift the direct burden of the [regulation] from the companies' New York customers to their out-of-State customers." *Shell Oil Co. v. N.Y. State Tax Comm'n*, 91 A.D.2d 81, 93 (N.Y. App. Ct. 1983).

54. Accordingly, the Act violates the Commerce Clause because it has the practical effect of discriminating against interstate commerce.

THIRD CAUSE OF ACTION
(42 U.S.C. § 1983 and 42 U.S.C. § 1988)

55. AAM re-alleges and incorporates herein by reference the allegations of the preceding paragraphs of this Complaint.

56. By seeking to implement and enforce the anti-pass-through provisions of the Act, Defendants, acting under color of state law, have violated and, unless enjoined by this Court, will continue to violate the rights of AAM members to engage in interstate commerce free from unconstitutional state discrimination in violation of the Commerce Clause.

57. An actual "Case or Controversy" exists because the Act's unconstitutional provisions create a genuine, credible, and immediate threat that Defendants—acting in their official capacities under color of state law—will violate the constitutionally protected rights of AAM and its members.

58. AAM accordingly seeks a declaration that Defendants' implementation or enforcement of the Act's anti-pass-through provisions would violate 42 U.S.C. § 1983. AAM also seeks reasonable attorneys' fees pursuant to 42 U.S.C. § 1988.

PRAYER FOR RELIEF

WHEREFORE, AAM prays:

A. For a declaration, pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, that the anti-pass-through provisions of the Act violate the United States Constitution, including but not limited to the Commerce Clause, and are therefore void and unenforceable;

B. For a preliminary injunction prohibiting Defendants from implementing and enforcing the anti-pass-through provisions of the Act;

C. For a permanent injunction prohibiting Defendants from implementing and enforcing the anti-pass-through provisions of the Act;

D. For such costs and reasonable attorney's fees to which it might be entitled by law; and

E. For any other relief that the Court deems just and proper.

Dated: September 7, 2018
New York, NY

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